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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,203	01/29/2001	Sharron Gaynor Penn	AEOMICA-1	7320

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Amersham Biosciences Corp
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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,203

Applicant(s)

PENN ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-67 and 70-104 is/are pending in the application.
- 4a) Of the above claim(s) 15-60 and 82-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-67, 70-81 and 93-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/10/04; 2/14/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicants' arguments, filed 9 February 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 15-67 and 70-104 are currently pending. Claims 1-14, 68 and 69 have been cancelled. This application contains claims 15-60 and 82-92 drawn to an invention nonelected with traverse in the reply filed 10 November 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 15-60 and 82-92 remain withdrawn.

Information Disclosure Statement

The Information Disclosure Statements filed 10 September 2004 and 14 February 2005 have been considered. Signed copies of PTO Forms 1449 are included with this Office Action.

Claim Rejections - 35 USC § 101

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

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"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-67, 70-81, and 93-104 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the Office Action of 29 January 2004.

Claims 61-67, 70-81, and 93-104 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Applicant's Arguments

Applicant argues the following, some of which have been previously addressed in the Office Action mailed 9/9/04:

1) Applicant argues that "the single exon nucleic acid microarrays of the instant application contains probes derived from genomic sequence of at least one predicted exon of a eukaryotic genome. The probes of the claimed microarray are not from any random "fragments of genomic DNA from open reading frames of eukaryotic genome". The probes are identified by gene prediction programs and/or cross species comparative genomics sequence analysis. The claimed microarray with these selected probes provides a valuable resource for high throughput

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gene discovery, the identification of alternatively spliced exons within a gene, the confirmation of predicted genes and exons, as well as providing expression verified single exon probes”.

This is not found persuasive. There is no indication in the specification as to what expression pattern, for instance, could be assessed. Any nucleic acid array may be used for this purpose. The specification fails to disclose specific association of any specific gene expression pattern with any real world utility. For what is this invention applicable or useful? Applicant states that it would be useful for “gene discovery”. However, Applicant is reminded that such statements (i.e. research tool) are not helpful in determining utility (MPEP 2100). The need for further research to establish a use does not constitute a substantial utility.

In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., “high throughput gene discovery, spliced exon identification, and single exon nucleic acid microarrays) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 61, for instance, recites “at least one” and “at least 50% of probes include genomic sequence of no more than one said exon”, which means that the array can have probes to multiple exons. Furthermore, Claim 65 limits the array to probes which include exons from all chromosomes.

2) Applicant further submits that the claimed microarrays have a well-established utility and provides several publications in supposed support of this assertion. For example, Applicant encloses a review article entitled “Microarrays: Biotechnology's Discovery Platform”, by Shena et al. (Trends in Biotechnology, Vol. 16, pages 301-306). Applicant points to a statement which

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says “advances in microarray technology enable massive parallel mining of biological data, with biological chips providing hybridization-based expression monitoring, polymorphism detection, and genotyping on a genomic scale”. Although interesting scientifically, this does not provide a specific or substantial utility to the claimed generic invention. The instant claims do not recite expression monitoring of a specific gene or gene set, nor do they recite polymorphism detection, or genotyping. The uses in the prior art associated with the claimed microarrays do not impart utility to the claimed invention.

3) Applicant again asserts that the claimed microarray may have utility in assessing gene expression patterns. It is noted that one of skill in the art would not know how to establish a meaningful result for non-specific single exon sequences, as contemplated herein. For example, if one fragment of a particular sequence were attached to the microarray in the instant invention and a researcher observed that upon exposure to a certain compound, expression were increased, how would one of skill in the art be able to determine if that increase were meaningful based upon the teachings in the specification? Other factors may have to be considered, such as type of compound, length of exposure etc... The specification provides no explanation of how to interpret results in a meaningful way such that the instant microarray would be useful as a research tool to analyze gene expression patterns. The specification only seems to indicate that the disclosed microarrays could be used in the discovery process, without providing any “real world context”.

4) Applicant contends that some of the microarray utilities disclosed in the instant application are “high throughput gene discovery”, “identification of splice sites, or the verification of expression of putative exons. The claimed microarrays are not supported by a

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specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any microarray. The research contemplated by applicant(s) to discover genes, does not constitute a specific and substantial utility. Potential uses for microarray high throughput or splice site identification do not provide an immediate benefit. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such microarrays. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed microarrays such that another non-asserted utility would be well established for the microarrays.

For the reasons stated above, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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No claims are allowed.

The rejections under 35 USC 112, 2nd paragraph have been withdrawn in view of Applicant's amendments.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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May 11, 2005
Lori A. Clow, Ph.D.
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Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/12/05